UPDATE ON GAINING APPROVAL FOR CLINICAL RESEARCH THROUGH THE HEALTH RESEARCH AUTHORITY (HRA)

Prepared by the Clinical R&D Office, Royal Marsden

On 25\textsuperscript{th} November 2015 we notified you of the planned changes the Health Research Authority (HRA) is implementing to manage the way research approvals are processed. The programme of roll-out is being introduced in cohorts with Cohort 3, the first to impact on research at RM and ICR, implemented on 30\textsuperscript{th} November 2015. Cohort 3 is for new multi-centre non-interventional research.

To date no RM/ICR sponsored studies have been through HRA Approval, but it has now been announced by the HRA that from 1\textsuperscript{st} April 2016 all studies will be required to go through the HRA Approval process.

**What type of research requires HRA approval from 1\textsuperscript{st} April?**

1. All new studies in cohorts 1 – 5 which includes single-centre studies. For further information on cohort definitions please go to [http://www.hra.nhs.uk/documents/2016/02/hra-approval-cohort-definitions.pdf](http://www.hra.nhs.uk/documents/2016/02/hra-approval-cohort-definitions.pdf)

2. All studies where an IRAS (Integrated Research Application System) submission has been made and REC (Research Ethics Committee) (and MHRA (Medicines and Healthcare Products Regulatory Agency) approval if required) may already be in place, but where no Site Specific Information (SSI) Form has been submitted.

3. All commercially sponsored research studies.

4. All amendments for new and existing studies.

For RM/ICR sponsored studies, the following arrangements will apply:

1. For multi-centre studies, where the amendment is to add a new site then the Statement of Activities and Schedule of Events will need to be submitted as part of the amendment documentation set

2. For single-centre studies requesting multi-centre status a Statement of Activities and Schedule of Events will need to be prepared and submitted as part of the amendment documentation set

The only exception is for those studies being undertaken for an educational qualification, research databases or research tissues banks.

*HRA approval is open for applications now in Cohorts 4 and 5 – however if you wish to put a study from these cohorts through HRA Approval before 1\textsuperscript{st} April please email the HRA* [hra.approvalprogramme@nhs.net](mailto:hra.approvalprogramme@nhs.net) *and notify the R&D Office via the generic email* [research&development@rmh.nhs.uk](mailto:research&development@rmh.nhs.uk) *so that they can support you through the process.*
**What other major changes will there be from 1st April?**

1. NIHR CSP (The Coordinated System for Gaining NHS Permission) will cease to exist. All study documentation required by participating sites will be provided by the sponsor/representative.

2. SSI forms are no longer required for sites in England, but will be required for sites in the devolved nations (Scotland, Wales and Northern Ireland).

3. For non-commercial studies a Statement of Activities and Schedule of Events will need to be completed by the Sponsor for multi-centre studies, submitted as part of the documentation set to the HRA for review and then sent to the sites. There will be a need to engage with Finance and Contracts at an earlier stage.

4. There will be a combined IRAS application for REC and HRA assessment.

5. HRA approval will only be issued once REC (and MHRA approval if required) has been given. The clinical trial application (CTA) to the MHRA will continue to be a separate process from HRA Approval, but the HRA will be working closely with them.

**What doesn’t change?**

1. The Committee for Clinical Research (CCR), for applying for RM/ICR sponsorship and the Trial Set-Up Meeting (TSM) for hosted interventional studies will continue with their current function, although documentation required to be submitted may change.

2. Pharmacy and Radiology technology review is likely to remain at site level until further notice as the process for central review by the HRA is not currently in place.

3. Contacting Central Booking Service (CBS) for REC review. This should be carried out prior to electronic submission via IRAS to the HRA. The CBS will continue to issue you with a REC reference number to insert on the IRAS Form prior to submission.

**Future Plans**

The Clinical R&D Office will issue guidance for hosted studies and support people through the application process for sponsored studies, developing guidance as studies go through this new HRA Approval system. The HRA will continue to develop their processes and documentation as more studies go through HRA approval so both HRA and R&D guidance is subject to change until the process is embedded. Please always refer to the latest guidance on the Clinical R&D intranet site or contact the Clinical R&D Office if you require clarification. For updates from the HRA please go to http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance

**Please note that no clinical research should be undertaken at RM/ICR without email confirmation from the Clinical R&D Office that it can commence.**

11th February, 2016